Fax

Roseanne Freese

07/25/2003 03:51 PM

To: fdadockets@oc.fda.gov
cc: dwiggin@cfsan.fda.gov, Susan Reid/ITP/Fas@Fas, Deborah Thompson/ITP/Fas@Fas
Subject: Affidavit Regarding WTO/SPS/USA/703 and 704 (Bioterrorism)

Dear Sir/Madame:

I am writing to swear and attest that a set of comments on WTO/SPS/USA/703 and 704 (Docket #2002N-0277 and #2002N-0275) consisting of an 11-page fax sent by the Government of Japan to the USDA Foreign Agricultural Service Food Safety and Technical Services Division were received on Monday, July 7, 2003, the last day allowed for public comment on the two notifications. However, due to severe staff shortage and my own travel and unexpected illness, I was not able to relay these comments from the U.S. Enquiry Point to the Food and Drug Administration. I will fax this affidavit and the 11-page set of comments received from the Government of Jpaapn over to your agency via fax number 301-827-6870. If you have any questions, please contact me at the number below.

Roseanne Freese

Roseanne Freese
United States Sanitary Phytosanitary Enquiry Point Officer
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ATTN: John Jones
ATTN: Debbie Suberg
Virgin

Rosie - Pls pass to FDA

of 11 page

TO : USDA/FAS/FSTSD
Stop 1027, Room 5545 South Agricultural Building
(PHONE (202) 720 - 2239 FAX (202) 690 - 0677)

CC : Mr. Brian Grunenfelder
Director, Asia and Americans Division
Foreign Agricultural Service, USDA
(PHONE (202) 720 - 1289 FAX (202) 690 - 1093)

FROM : Tadashi SATO, Agricultural Attache
Embassy of Japan
(PHONE (202) 238 - 6721 FAX (202) 265 - 9473)
tadsato @ embjapan.org

DATE : July 7, 2003

Comments on Administrative Detention from GOJ. Please include in packets.

NUMBER OF PAGES INCLUDING THIS COVER SHEET : 11

Dear Sir / Madame :

Please find attached the comments of Japanese Government on the United States' proposed regulations "Administrative Detention of Food for Human or Animal Consumption" (G/SPS/N/USA/704) and "Establishment and Maintenance of Records" (G/SPS/N/USA/703) under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. We will send the same paper to FDA and USTR, as well.

Along with our previously submitted comments on the proposed regulations "Registration of Food Facilities" and "Prior Notice of Imported Food," we would appreciate your consideration and response to these questions and comments.

If you have any questions about the comments, please let me know.

With best regards,

Fax # 301-436-2618

July 7, 2003

Questions and Comments by the Government of Japan on the United States' Proposed Regulation "Administrative Detention of Food for Human or Animal Consumption (Article 303)" Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (DOCKET No. 02N-0275)

The Government of Japan appreciates the opportunity to provide comments on the United States' proposed regulation of "Administrative Detention of Food for Human or Animal Consumption" under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, published in the United States' Federal Register May 9, 2003 and notified to the WTO Members on May 14, 2003 (G/SPS/N/USA/704). The followings are our questions and comments.

1. Questions

(1) We regard the condition for detention, "credible evidence or information... indicating the article presents a threat of serious adverse health consequences or death to humans or animals," as unclear. Please provide us with several examples constituting "credible evidence or information."

(2) Specifically, for what purpose and how is an inspection carried out? While it would naturally take several days for the inspection on certain items to yield results, would the freight have to be kept detained until the results of the inspection is obtained?

(3) Under the proposed regulation, would the FDA send the Detention Order directly to the owner, operator, or agent in charge of the place where the article of food is located even in cases where the owner, operator, or agent does not reside in the U.S.?

2. Comments

(1) We request that the FDA ensure the proposed regulation to be consistent with the WTO agreement and not to create an undue burden on trade.

(2) The WTO Member countries have to apply measures only to the extent necessary to protect human, animal or plant life or health, based on sufficient and scientific grounds under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). In light of the obligation, please clarify the scientific grounds the FDA takes into account in introducing this proposed

regulation, and whether the FDA applies the proposed regulation only to the extent necessary to accomplish its objectives.

(3) We request that for those exporters who need to ask about "Administrative Detention of Food for Human or Animal Consumption" under this proposed regulation, the FDA establish consultation service staffed with Japanese speakers at the U.S. embassy and consulates in Japan.

(4) The FDA should ensure transparent implementation of this section in order to prevent this section from becoming unnecessary trade barrier or restrictions on the activities of private businesses.

(5) In addition to (4) above, when the FDA orders the detention of the products at the port for unloading, the FDA should publish the fact of detention through the Import Refusal Report.

(6) When the FDA gets any information relating to the detention, it should provide such information to the parties concerned and their countries immediately.

(7) The regulation should stipulate that sufficient compensation for the detention should be provided when the detention is found unjust.

(8) In a case where a foreign manufacturer makes proper registration for its export to the U.S. while the manufacturer's importer/exporter makes incomplete registration and the export is detained for inspection, the regulation should stipulate that the detention should not affect the export of the manufacturer itself or via an importer/exporter other than the importer/exporter which made the incomplete registration.

July 7, 2003

Questions and Comments by the Government of Japan on the United States' Proposed Regulation "Establishment and Maintenance of Records (Article 306)" Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (DOCKET No. 02N-0277)

The Government of Japan appreciates the opportunity to provide comments on the United States' proposed regulation of "Establishment and Maintenance of Records" under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, published in the United States' Federal Register May 9, 2003 and notified to the WTO Members on May 15, 2003 (G/SPS/N/USA/703). The followings are our questions and comments.

1. Questions

(1) Please clarify the definition and content of "packing."

Before going through the customs clearance, packed freights will be further fortified, for instance, by hard cartons or wooden frames, in order to strengthen resistance to frictions and strikes during exporting process. In this case, are hard cartons and wooden frames that never contact food, as they merely fortify the "packed" freights, also included in "packing?"

(2) Please clarify the definition and content of "holding."

In Japan, in order to go through the customs clearance for the exports to the U.S., freights must be transferred into bonded warehouses or bonded area and be left there until acquiring the permission of export. Is the restoration only for receiving the permission of export also included in "holding?"

(3) 21CFR113 requires automatic detention of canned foods when deviation of thermal processing or sealing is detected, because the deviation could be life-threatening. Will the Bioterrorism Act also order the automatic detention or inspection of records, when deviation in such critical control points is detected?

(4) Would the FDA directly request for records or directly inspect the records of firms that are located outside the U.S.? If not, how would the FDA go about obtaining such records or making such inspections?

(5) Will the FDA accept information by facsimile or e-mail written in Japanese?

(6) Some products are forwarded from the original factory to the last shipment via several distribution bases. Do all of these records have to be maintained? (In relation to Section 305, is registration required for these relay facilities?)

(7) Will the records be published?

(8) When the FDA requests the access to the records, how will the time difference between foreign countries and the U.S. be dealt with when considering the time frame required by the regulation?

(9) This Article 306 stipulates that a foreign facility which holds food to be consumed in the U.S. must establish and maintain records at the place of the facility. In this case, we presume that such a foreign facility is equal to the one which is required to be registered in Article 305, according to the explanation by FDA in relation to this regulation draft, "Proposed Rules" page 25191.

In Japan, however, a warehouse company is in a position only to hold goods deposited by the owner of the goods, and it is not necessarily in a position to obtain information of the goods with regard to exports, such as whether they are destined to the U.S. or not. Therefore, we are of the view that an owner of goods, an exporter in Japan or an importer in the U.S. should be defined as "register facilities" under Article 305.

Further, it is also our view that, as in the case of Article 305, an owner of goods, an exporter in Japan or an importer in the U.S. not a warehouse company, which hold information about export of foods, should be reqnired to establish and maintain records at the place of a foreign facility. Please clarify if this understanding is correct or not.

(10) According to Sec. 1. 363, failure to establish and maintain records will be "prohibited acts." Will there be any criminal charges filed in administrative sanctions imposed against those who committed "prohibited acts" even if they do not reside in the U.S.?

2. Comments

(1) We request that the FDA ensure the proposed regulation to be consistent with the WTO agreement and not to create an undue burden on trade.

(2) The WTO Member countries have to apply measures only to the extent necessary to protect human, animal or plant life or health, based on sufficient and scientific grounds under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). In light of the obligation, please clarify the scientific grounds the FDA takes into account in introducing this proposed regulation, and whether the FDA applies the proposed regulation only to the extent necessary to accomplish its objectives.

(3) We request that for those who need to ask about "Establishment and Maintenance of Records" under this proposed regulation, the FDA establish consultation service staffed with Japanese speakers at the U.S. embassy and

consulates in Japan.

(4) The FDA should only require minimum information necessary to be kept as record, so as not to create an undue burden on private businesses.

(5) The FDA should give appropriate guidance to private businesses in establishing and maintaining the records smoothly, for example, by showing a model of how records should be kept.

(6) The scope of the contents of the record required by the Bioterrorism Act should be within those required by current 21 CFR113, 21CFR114, and 21CFR123 for the seafood HACCP regulations.

(7) In requiring a record of raw material of a product, the FDA should limit its requirement to that of major ingredients of the product.

(8) With regard to the requirements for the creation and the maintenance of records needed to determine the immediate previous sources and the immediate subsequent recipients of food (i.e., one up, one down) for "persons other than transporters," the FDA should not require any further information not directly linked to the objectives of the regulation, such as business situation or conditions of the "source" and "recipients."

(9) The FDA should not require manufacturing and processing records of fresh agricultural products that are sold as such on the market.

(10) Under the article, it is required to maintain the records containing ingredients used in a food product. Though the quantitative formula is excluded, we suppose it will result in a part of trade secrets being recorded in terms of e.g. the combination of spices. Therefore, we regard it sufficient to maintain the records on Nutrition Facts, (Supplement Facts, or its equivalents indicated on final products).

(11) In other regulations concerning public health security and bioterrorism such as Article 307, foreign facilities will not be subject to criminal charges in administrative sanctions. It would therefore be appropriate in this regulation (Article 306) to take the same approach not to impose any criminal charges in administrative measures to foreign facilities.

平成１５年７月７日

米国におけるバイオテロ対策のための食品安全規制の強化に係る日本政府のコメント及び質問－行政措置による留め置き－　(DOCKET No. 02N-0275)

米国の「公衆の健康安全保障及びバイオテロへの準備及び対策法（２００２年６月成立)」に基づく、新たな施行規則案の一つである「行政措置による留め置き」に関し、日本政府は、５月９日付で米国官報に掲載され、５月１４日付でＷＴＯ・ＳＰＳ通報（G/SPS/N/USA/704）された当該施行規則案に対し、コメントを行う機会が提供されたことに感謝する。以下は、我が国政府の質問及びコメントである。

１．質問

（１）detentionを行う要件、"credible evidence or information indicating..... humans or animals"の内容が不明確ではないかと考えられる。人、動物の健康・生命に脅威を及ぼす恐れがあると認める場合の条件として具体的に想定される事態はどのような事態か。

（２）具体的にどのような目的でどのような検査がされるのか。検査項目によっては結果が出るのに数日を要するものもあると考えられるが、その間積荷は留置されるのか。

（３）同規制の下では、ＦＤＡは、食品の所在地の所有者、業者又は代理業者が米国外に所在する場合も、留め置き命令を当該所有者、業者又は代理業者に直接送付することが想定されているのか。

２．意見

（１）今回の施行規則案が貿易上の不当な制限とならないよう、ＷＴＯ協定との整合性を確保すべきこと。

（２）ＳＰＳ協定上、各国が導入する措置は十分な科学的根拠に基づき必要な限度においてのみ適用される必要があるとされているところ、本施行規則を導入するに際し

るか否かについて説明願いたい。

（３）今回の施行規則案の「行政措置の留め置き」について日本国内の輸出業者が日本語で相談できる窓口を日本国内の米国大使館及び米国領事館に設けること。

（４）不必要な貿易障壁及び企業活動への制限とならないよう、本条項の運用について透明性の確保を図ること。

（５）（４）に加えて、陸揚げ港で留置を受けた場合、従来から公表されている輸入停止情報（Import refusal report）でも公表すること。

（６）ＦＤＡは、留置に関する情報を得た場合、直ちに関係者・国への情報提供を行うこと。

（７）留置処分を不当として不服申し立てし、これが承認・解除された場合、十分な補償が行われるように規定すること。

（８）製造業者が適切に登録等を行っているにもかかわらず、輸出入業者の登録等の不備により留置が行われる場合、製造業者が自らあるいは他の輸出入業者を通じて行う米国への輸入に対して、留置等の影響が無いよう規定すること。

平成１５年７月７日

米国におけるバイオテロ対策のための食品安全規制の強化に係る日本政府のコメント及び質問－記録の作成及び維持－ (DOCKET No.02N-0277)

米国の「公衆の健康安全保障及びバイオテロへの準備及び対策法（２００２年６月成立)」に基づく、新たな施行規則案の一つである「記録の作成及び維持」に関し、日本政府は、５月９日付で米国官報に掲載され、５月１５日付でＷＴＯ・ＳＰＳ通報（G/SPS/N/USA/703）された当該施行規則案に対し、コメントを行う機会が提供されたことに感謝する。以下は、我が国政府の質問及びコメントである。

１．質問

（１）「packing」の定義、内容を明確にしていただきたい。

・貨物を輸出しようとする場合、既に梱包されている保管貨物に対して、さらに輸出に耐え得る養生を施す梱包(ハードカートンに詰める、木枠をつけるなど)を行ってから輸出通関手続きを行うことになる。こうした直接食品に触れることのない輸出用梱包もpackingに含まれるのか。

（２）「holding」の定義、内容を明確にしていただきたい。

・米国向け輸出通関手続きを行うためには、保税蔵置場（bonded warehouse or bonded area）へ貨物（食品）を搬入し、輸出許可が出るまで蔵置しなければならない。この通関手続き待ちのためだけにある蔵置もholdingに含まれるのか。

（３）21CFR Part 113に関わる缶詰では、加熱殺菌や密封の逸脱（Deviation of thermal processing and Sealing）がみられた場合は、生命に重大な問題を起こす可能性があるという理由で自動停止処分（automatic detention）を受ける。このBioterrorism Actでもこうした重要管理点（Critical control point）の逸脱は、記録の閲覧や自動停止処分の対象にされるのか。

（４）ＦＤＡは、米国外に所在する企業についても直接記録を請求したり、記録の検査を行ったりするのか。そうでない場合には、どのようにして記録を請求したり、記録の検査を行ったりするつもりか。

（５）情報伝達は、日本語のＦＡＸ・メールなどでも支障ないか。

（６）製造された食品が工場出荷後、最終船積みまでに複数の物流拠点を経由する場合、それらについての記録もすべて保持しておくことが必要なのか。またこのことは３０５条にも関連するが、これら中間施設も事前登録が必要なのか。

（７）求められる記録の内容は公開されることがあるか。

（８）記録の開示を求められた場合、時差の関係上米国時間で要求されるアクセス可能時間帯に完全に対応するのは不可能ではないか。

（９）本条において、外国において記録の作成及び維持が義務付けられる対象として、米国における消費に向けた食品を保管する「外国施設」があげられているが、この場合の「外国施設」は今回の規則案に関するＦＤＡの説明によれば、３０５条において登録することを求められている施設を指すものと思われる（"Proposed Rules" Page 25191）。

そもそも営業倉庫の場合、倉庫業者は荷主の指示を受けて貨物を保管しているにすぎないことから、保管した貨物の仕向け地が米国かどうかといった輸出に関する情報を必ずしも把握できず、３０５条における施設の登録義務者は荷主又は輸出入業者であると考えている。

同様に本条における記録の作成及び維持の義務についても、当該食品の輸出に関する情報は荷主又は輸出入業者が持っているところであり、３０５条と同様に荷主又は輸出入業者が負うべきであると考えるがどうか。

（１０）Sec. 1. 363によれば、記録の作成及び維持の不履行は「禁止された行為」となるとされている。この「禁止された行為」に該当するとされた場合、当該業者が米国内に所在しない場合でも刑事上、あるいは行政上の処罰の対象となるのか。

２．意見

（１）今回の施行規則案が貿易上の不当な制限とならないよう、ＷＴＯ協定との整合性を確保すべきこと。

（２）ＳＰＳ協定上、各国が導入する措置は十分な科学的根拠に基づき必要な限度においてのみ適用される必要があるとされているところ、本施行規則を導入するに際して考慮した科学的根拠、及び本施行規則が目的達成のために必要最小限のものであるか否かについて説明願いたい。

（３）今回の施行規則案の「記録の保管及び維持」について日本国内の輸出業者が日本

語で相談できる窓口を日本国内の米国大使館及び米国領事館に設けること。

（４）記録の作成に当たり、企業の過重な負担とならないよう、具体的な記録内容について必要最小限のものとすること。

（５）ＦＤＡは模範記録例を示す等により、円滑な記録の作成と保管ができるよう企業を適切に指導すること。

（６）バイオテロ法で要求される記録内容は、現行の21CFR Part 113、Part 114及びシーフードHACCP規則（21CFR Part 123）における記録内容よりも広範なものとならないこと。

（７）原材料の記録については、当該製品の主たる原料に限定すること。

（８）製造施設における前後の取引先（immediate previous sources and the immediate subsequent recipients of foods）の特定を可能とする記録が要求されているが、これ以上の情報（例えば取引先の経営や業務に係る情報等）について、記録や情報提供の義務が課されないようにすること。

（９）加工を行っていない生鮮農産物については、製造や加工に係る記録は不必要とすること。

（１０）記録の保持で、「原材料の特定に関する記録は必要」とあるが、数量的フォーミュラが除外されるとしても、香料等の組み合わせについては、トレードシークレットに関わる部分を記述することになるので、最終製品に表示するNutrition Facts（もしくはSupplement Facts）と同等のもので充分と思われること。

（１１）バイオテロ対策に関する他の規制（３０７条）においても、外国施設は刑事罰あるいは行政処分の対象外とされており、この規制（３０６条）においても同様に扱われることが望ましい。